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SERIAL NUMBER	FILING DATE	FIRST NAMED AP	PLICANT		ATTORNEY DOCKET NO.
08/417.174	04/05/95	KAWAKAMI		Y	2026-4124US1
				HUFF,S 8	EXAMINER
I PATENT BRAI	NCH	18N1/0703			
OFFICE OF TECHNOLOGY TRANSFER				ART UNIT	PAPER NUMBER
	NSTITUTES OF	F HEALTH BOX 13 ARD SUITE 325		1806	/
ROCKVILLE			`	DATE MAILED:	07/03/96

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

Application No. **08/417,174**

Applicant(s)

Kawakami et al

Office Action Summary Examiner

Sheela J. Huff

Group Art Unit 1806



X Responsive to communication(s) filed on Feb 23, 1996	•				
☐ This action is FINAL .					
☐ Since this application is in condition for allowance except for form in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.E.					
A shortened statutory period for response to this action is set to expision is set to expision from the mailing date of this communication. Failure to reapplication to become abandoned. (35 U.S.C. § 133). Extensions of 37 CFR 1.136(a).	spond within the period for response will cause the				
Disposition of Claims					
X Claim(s) 1-38	is/are pending in the application.				
Of the above, claim(s)	is/are withdrawn from consideration.				
Claim(s)	is/are allowed.				
Claim(s)	is/are rejected.				
☐ Claim(s)	is/are objected to.				
Application Papers					
See the attached Notice of Draftsperson's Patent Drawing Re-					
☐ The drawing(s) filed on is/are objected					
☐ The proposed drawing correction, filed on is ☐ approved ☐ disapproved.					
☐ The specification is objected to by the Examiner.					
\square The oath or declaration is objected to by the Examiner.					
Priority under 35 U.S.C. § 119					
Acknowledgement is made of a claim for foreign priority under	er 35 U.S.C. § 119(a)-(d).				
☐ All ☐ Some* ☐ None of the CERTIFIED copies of the	priority documents have been				
received.					
received in Application No. (Series Code/Serial Number)					
\square received in this national stage application from the Inter	rnational Bureau (PCT Rule 17.2(a)).				
*Certified copies not received:					
☐ Acknowledgement is made of a claim for domestic priority un	der 35 U.S.C. § 119(e).				
Attachment(s)					
☐ Notice of References Cited, PTO-892					
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s).					
☐ Interview Summary, PTO-413					
Notice of Draftsperson's Patent Drawing Review, PTO-948 Notice of Draftsperson's Patent Drawing Review, PTO-948 Notice of Draftsperson's Patent Drawing Review, PTO-948					
☐ Notice of Informal Patent Application, PTO-152					
SEE OFFICE ACTION ON THE F	FOLLOWING PAGES				

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Part III DETAILED ACTION

Election/Restriction

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
- Group I. Claims 1-14, drawn to peptides of MART-1, classified in Class 530, subclass 328 and 350+.
- **Group II.** Claims 15-26, drawn to peptides of gp100, classified in Class 530, subclass 328.
- Group III. Claims 32-35, drawn to nucleic acid sequences and vectors, classified in Class 536, subclass 23.1+.
- **Group IV.** Claims 36-38, drawn to antibodies, classified in Class 530, subclass 387.7.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I-IV are disclosed as different combinations which are not connected in design, operation or effect. These combinations are independent if it can be shown that (1) they are not disclosed as capable of use together, (2) they have different modes of operation, (3) they have different functions, or (4) they have different effects. (MPEP 806.04, MPEP 808.01). In the instant case the combinations are unrelated in chemical composition and structure, in physicochemical properties and in function.

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Specifically, the nucleic acid sequence of Invention III can be used to synthesize a protein whereas the antibody of Invention IV or the proteins or peptides of Inventions I and II cannot. The antibody of Invention IV can be used to produce an immunogen for making anti-idiotype antibodies whereas the nucleic acid sequence of Invention III cannot. The proteins and peptides of Invention I and II can be also be used as an immunogen where as the nucleic acid sequence of Invention III cannot. The protein and peptides of Invention I and II are different amino acid sequences and therefore are chemically and structurally different. Similarly, the antibody of Invention IV and the proteins or Inventions I or II are also chemically and structurally different products. Thus, the products of Inventions I-IV are separate and patentably distinct from each other.

- 3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
- 4. Because these inventions are distinct for the reasons given above and the search required for Invention I is not required for Inventions II-IV, the search required for Invention II is not required for Inventions I and III-IV, the search required for Invention III is not required for Inventions I-II and IV, the search required for Inventions I-II and IV, the

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I-III restriction for examination purposes as indicated is proper.

Election of Species

- 5. This application contains claims directed to the following patentably distinct species of the claimed invention:
- a. If applicant elects either Group I or Group II, then applicant should elect either MART-1 or gp100 of claims 27-31. For example, if applicant elects Group I, then claims 27-31 (referring to MART-1) will be examined with Group I.
- b. If applicant elects Group III, then applicant should elect either MART-1 or gp100.
- c. If applicant elects Group VI, then applicant should elect either MART-1 or gp100.

As explained above, MART-1 and gp100 are distinct proteins encoded by distinct nucleic acid sequences and thus are chemically and structurally unrelated.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, either claims 1-14 or claim 15-26 is generic.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An

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argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

6. No attempt was made to call the attorney of record to request an oral election to the above restriction requirement because of the complexity of the restriction.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J. Huff whose telephone number is (703) 305-7866. The examiner can normally be reached on Monday-Thursday from 6:30am to 3:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marian Knode, can be reached on (703) 308-4311. The FAX phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Sheela J. Huff 6/28/96

Sheela J. Huff
Patent Examiner
Group 1800